UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

GLENDA JIMMO, K.R. by her guardian KENNETH ROBERTS, MIRIAM KATZ, EDITH MASTERMAN, MARY PATRICIA BOITANO, NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE, NATIONAL MULTIPLE SCLEROSIS SOCIETY, PARKINSON'S ACTION NETWORK, PARALYZED VETERANS OF AMERICA, AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION, ALZHEIMER'S ASSOCIATION, UNITED CEREBRAL PALSY, and ROSALIE MCGILL, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	Case No. 5:11-cv-17
KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services,	)	
Defendant.	)	

OPINION AND ORDER DENYING IN PART AND GRANTING IN PART DEFENDANT'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION AND DENYING DEFENDANT'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM
(Doc. 25)

This matter came before the court on the motions to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), and for failure to state a claim under Fed. R. Civ. P. 12(b)(6). filed by Defendant, the Secretary of Health and Human Services Kathleen Sebelius ("the Secretary") in her official capacity (Doc. 25). The Secretary seeks dismissal of the Amended Complaint filed by six individual Medicare beneficiaries (the "Individual Plaintiffs") and seven national organizations (the "Organizational Plaintiffs") (collectively, "Plaintiffs"). Plaintiffs oppose dismissal.

The crux of the Amended Complaint is an allegation that the Secretary has adopted an unlawful and clandestine standard to determine whether Medicare beneficiaries are entitled to coverage, resulting in the wrongful termination, reduction, and denial of Medicare coverage for beneficiaries with medical conditions that are not expected to improve. Plaintiffs seek to certify a nationwide class and request, among other relief, an injunction or writ of mandamus enjoining the Secretary from applying this alleged unlawful standard.

The court heard oral argument on these motions on July 14, 2011, and the parties completed their supplemental briefing on August 8, 2011. Plaintiffs are represented by the Center for Medicare Advocacy, Inc. and Vermont Legal Aid, Inc. The Secretary is represented by Steven Y. Bressler, Esq. and Tamra Moore, Esq.

For the reasons set forth below, the Secretary's motion to dismiss for lack of subject matter jurisdiction is DENIED IN PART AND GRANTED IN PART, and the Secretary's motion to dismiss for failure to state a claim is DENIED.

I. The Amended Complaint.

The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395*iii* (the "Medicare Act"), "is the federal government's health-insurance program for the elderly." *Conn. Dept. of Soc. Servs. v. Leavitt*, 428 F.3d 138, 141 (2d Cir. 2005). It is administered by the Center for Medicaid and Medicare Services ("CMS"), which is a component of HHS.

Under the Medicare Act, payment is precluded for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). Coverage determinations are required by law to be conducted on an individualized basis and cannot be the subject of rules of thumb.

In their Amended Complaint, Plaintiffs allege that the Secretary "imposes a covert rule of thumb that operates as an additional and illegal condition of coverage and results in the termination, reduction, or denial of coverage for thousands of Medicare beneficiaries annually." (Doc. 13 ¶ 1.) This additional condition of eligibility, which

Plaintiffs allege is primarily implemented at the lower levels of Medicare's administrative review process, denies coverage where the beneficiary needs "maintenance services only," has "plateaued," or is "chronic," "medically stable," or not improving. (*Id.* ¶ 2.) Plaintiffs refer to this "covert rule of thumb" or "clandestine policy" as the "Improvement Standard." (*Id.* ¶¶ 2-3.)

Plaintiffs allege that, contrary to the Medicare Act and federal regulations, the Improvement Standard precludes coverage for beneficiaries with conditions that are not expected to improve or that have not improved over the course of treatment. They allege that the Improvement Standard has been implemented without proper rulemaking procedures against beneficiaries that have little or no understanding of its application and no ability or reasonable opportunity to confront it. According to Plaintiffs,

> [u]pon information and belief, it is the standard practice of providers, contractors, QIOs, QICs, and IREs to apply LCDs and internal guidelines and policies that establish the Improvement Standard as a rule of thumb on which Medicare coverage is conditioned, in disregard of the regulatory and manual provisions that require a coverage determination to be based on the beneficiary's individual condition and needs.

(*Id.* ¶ 44.) Plaintiffs further allege that because "the Secretary is aware that the Improvement Standard is consistently imposed by [] Medicare contractors," and because she "has not taken action to require that the proper policies be carried out," (*id.* ¶ 47), the "Improvement Standard . . . amounts to a clandestine policy that is condoned and implemented by the Secretary." (*Id.* ¶ 3.)

As grounds for relief, Plaintiffs assert that the Improvement Standard violates the Medicare Act and its regulations, the Administrative Procedure Act ("APA"), the Freedom of Information Act ("FOIA"), and the Due Process Clause of the Fifth Amendment. They seek a declaration that the Improvement Standard is unlawful and a permanent injunction or writ of mandamus prohibiting the Secretary from applying the Improvement Standard. Plaintiffs also seek an order directing the Secretary to, *inter alia*, review all adverse coverage decisions for the named plaintiffs and class members that rely on the Improvement Standard and to reissue those decisions without application of

the Improvement Standard. Furthermore, Plaintiffs seek a declaration ordering the Secretary to correct any written agency materials that may endorse the Improvement Standard. (*Id.* at 42-43.)

With regard to each of the named Individual Plaintiffs, Glenda Jimmo, K.R., Miriam Katz, Edith Masterman, Mary Patricia Boitano, and Rosalie McGill, the Amended Complaint describes the administrative process (or lack thereof) by which each beneficiary's claim for coverage was denied, the nature of the medical condition for which coverage was sought, and the manner in which the alleged Improvement Standard was invoked to deny coverage.

With regard to the Organizational Plaintiffs, National Committee to Preserve Social Security and Medicare, National Multiple Sclerosis Society, Parkinson's Action Network, Paralyzed Veterans of America, American Academy of Physical Medicine and Rehabilitation, Alzheimer's Disease and Related Disorders Association, Inc. d/b/a Alzheimer's Association, and United Cerebral Palsy, the Amended Complaint alleges the nature of each organization, its primary activities and mission, and the approximate number of its members who are Medicare beneficiaries. With the exception of American Academy of Physical Medicine and Rehabilitation ("AAPM&R"), Plaintiffs allege that at least one of their members would have standing to sue. Plaintiffs further allege that each Organizational Plaintiff provided notice to the Secretary and Donald Berwick, the CMS Administrator, that the Improvement Standard violates federal statutory, regulatory, and constitutional law and demanded that the Secretary and the CMS Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application." (*Id.* at ¶¶ 92, 101, 109, 117, 124, 132.)

II. Conclusions of Law and Analysis.

The Secretary moves to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), and for failure to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). Because the court "lacks the statutory or constitutional power to adjudicate" the merits of claims over which it does not have subject matter jurisdiction,

Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000), the court first addresses the Secretary's Rule 12(b)(1) motion.

A. The Secretary's Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction.

Plaintiffs assert jurisdiction under 42 U.S.C. § 405(g), which provides the court with jurisdiction to review the Secretary's "final decision[s]" on claims arising under the Medicare Act. Plaintiffs also invoke federal question jurisdiction under 28 U.S.C. § 1331, and mandamus jurisdiction under 28 U.S.C. § 1361.

With regard to Plaintiff Edith Masterman, the Secretary argues she has failed to satisfy the non-waivable requirement of presentment. With regard to Plaintiffs Miriam Katz,[1] Mary Patricia Boitano, and Rosalie McGill, the Secretary alleges they must exhaust their administrative remedies before § 405(g) can provide jurisdiction over their claims. With regard to Plaintiffs Glenda Jimmo and K.R., the Secretary argues that while they have exhausted their administrative remedies, they lack Article III standing to bring suit, and therefore this court cannot constitutionally adjudicate their claims.

The Secretary contends that 28 U.S.C. § 405(h) specifically excludes § 1331 as an avenue for judicial review of claims arising under the Medicare Act. Further, the Secretary argues that the nature of Plaintiffs' allegations and their requested relief renders the remedy of mandamus inappropriate in this case.

Finally, the Secretary argues that this court lacks subject matter jurisdiction over the Organizational Plaintiffs' claims because (1) Plaintiffs have not sufficiently alleged associational standing; and (2) even if standing is assumed, the Organizational Plaintiffs have not and cannot establish § 405(g) jurisdiction by presenting their claims to the Secretary and exhausting their administrative remedies.

Plaintiffs bear the burden of establishing this court's subject matter jurisdiction over their claims. *See Lujan v. Defenders of Wildlife*, 504 U.S 555, 561 (1992). When deciding a Rule 12(b)(1) motion "at the pleading stage" before any "evidentiary hearings

[1] As the named executor in her deceased husband David Katz's will, Plaintiff Miriam Katz is prosecuting this litigation on his behalf. (Doc. 13 ¶ 64.)

have been held," the court "must accept as true all material facts alleged in the [Amended C]omplaint and draw all reasonable inferences in [Plaintiffs'] favor." *Conyers v. Rossides*, 558 F.3d 137, 143 (2d Cir. 2009) (internal quotation marks and citation omitted). "Nevertheless, even 'on a motion to dismiss, courts are not bound to accept as true a legal conclusion couched as a factual allegation.'" *Id.* (quoting *Sharkey v. Quarantillo*, 541 F.3d 75, 83 (2d Cir. 2008) (other internal quotation marks omitted)).

1. 42 U.S.C. § 405(g) Jurisdiction.

The Secretary seeks dismissal on the grounds that all Plaintiffs (with the exception of Ms. Jimmo and K.R.) have failed to establish jurisdiction under 42 U.S.C. § 405(g). 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that 42 U.S.C. § 405(g) "to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984) (quoting 42 U.S.C. § 405(h)).[2] A claim arises under the Medicare Act when that statute "provides both the standing and the substantive basis for" the claim. *Weinberger v. Salfi*, 422 U.S. 749, 760-61 (1975). Section 405(g), in turn, provides that:

> Any individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced . . . in the district court of the United States for the judicial district in which the plaintiff resides[.]

42 U.S.C. § 405(g). The requirement of a "final decision by the [Secretary]" consists of two elements: (1) the "jurisdictional," non-waivable requirement that a claim has been presented to the Secretary, and (2) the "waivable" requirement that the administrative remedies prescribed by the Secretary have been exhausted. *See Mathews v. Eldridge*, 424 U.S. 319, 328-30 (1976); *Salfi*, 422 U.S. at 764-65. The exhaustion requirement may be

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[2] As applied to the Medicare Act by 42 U.S.C. § 1395ii, § 405(h) provides that: "No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act]."

waived by the Secretary, or, in appropriate circumstances, by the court. *See City of New York v. Heckler*, 742 F.2d 729, 736 (2d Cir. 1984) (internal citations omitted).

a. The Individual Plaintiffs' Claims under § 405(g).

The Secretary seeks dismissal of Ms. Katz, Ms. Masterman, Ms. Boitano, and Ms. McGill's claims for failure to establish subject matter jurisdiction under the Medicare Act pursuant to § 405(g). Plaintiffs do not dispute that their claims "arise under" the Medicare Act, and thus the exclusivity provisions of § 405(g) would normally apply. They point out that, with the exception of Ms. Masterman, the Individual Plaintiffs have all presented their claims to the Secretary. They also concede that with the exception of Ms. Jimmo and K.R., they have not exhausted their administrative remedies and received the Secretary's final decision with regard to their claims. However, based on the nature of their claims, they argue that the court should waive the exhaustion requirement.

Because presentment is non-waivable, the court turns first to Plaintiffs' contention that the exclusivity of § 405(g), as prescribed by § 405(h), should not apply to Ms. Masterman's claims because such application would deny her judicial review.[3]

i. Ms. Masterman's Presentment Requirement.

According to the Amended Complaint, the only home health agency ("HHA") in Ms. Masterman's geographic area refused to accept her as a patient because "Medicare will not pay for a chronic problem," and she needs long term care. (Doc. 13 ¶ 71.) As a result, no services have been provided, and no claim for coverage has been presented to the Secretary. Since only providers can seek an initial coverage determination, Ms. Masterman argues that the refusal to provide services effectively bars her from the administrative process, rendering it impossible for her to satisfy the jurisdictional presentment requirement of § 405(g).

The Secretary disagrees, arguing that Ms. Masterman has the ability to trigger administrative review by forcing her provider to make a claim for benefits. Although the

[3] In the alternative, Plaintiffs allege federal question jurisdiction for Ms. Masterman's claims under 28 U.S.C. § 1331.

Secretary concedes this procedure would require Ms. Masterman to assume liability for the cost of any uncovered services, the Secretary argues that this financial risk is insufficient to justify federal question jurisdiction.

In *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), the Court interpreted *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667 (1986), to hold that § 405(h) "does not apply . . . where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Illinois Council,* 529 U.S. at 19. Other courts have explained that this exception "applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court[;] . . . [t]he difficulties must be severe enough to render judicial review unavailable as a practical matter." *Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005). Under such circumstances, a plaintiff may invoke federal question jurisdiction under § 1331 to bring claims arising under the Medicare Act.

Although this case presents a close question, the court cannot conclude, based upon the record before it, that judicial review is unavailable to Ms. Masterman as a practical matter. As the Secretary points out, Ms. Masterman can force her HHA to submit a claim through a procedure known as "demand billing." A "demand bill" is a "claim submitted by an HHA to [CMS] for services or items that the HHA believes are not covered but which the HHA must submit to [CMS] at the request of the beneficiary[.]" *Lutwin v. Thompson*, 361 F.3d 146, 149 (2d Cir. 2004) (internal quotation marks and alterations omitted). To require submission of a demand bill, the beneficiary must agree to pay the HHA for services that CMS determines are not covered by Medicare. *See id.* A beneficiary has this option when an HHA "prospectively decline[s] to provide . . . services . . . when it conclude[s]," as Ms. Masterman's HHA did here, "that [CMS] would not cover those services. *Id.*[4] This would "trigger the administrative

[4] When an HHA declines to provide services because it believes that such services will not be covered by Medicare, CMS requires it to provide the beneficiary with a "Home Health Advance Beneficiary Notice." On this notice, the beneficiary may trigger demand billing by selecting the

process, at the end of which is judicial review of the Secretary's final decision." *Am. Chiropractic Ass'n*, 431 F.3d at 817. Some potential difficulty or financial hardship is generally not enough. *See Ringer*, 466 U.S. at 622, 625 (holding that Ringer's claim arose under the Medicare Act and required presentment even though "some . . . surgeons may well decline to perform the requested surgery because of fear that the Secretary will not find the surgery 'reasonable and necessary' and thus will refuse to reimburse them.").

Here, Ms. Masterman has not established that she is financially unable to reimburse her HHA in the event services are not covered or that demand billing is not available to her. She has thus not established that applying § 405(h) to her claims renders judicial review unavailable. Accordingly, Ms. Masterman is required to present her claims to the Secretary, and jurisdiction under both § 405(g) and § 1331 is not available. The Secretary's motion to dismiss Ms. Masterman's claim for lack of subject matter jurisdiction is therefore GRANTED.

ii. Waiver of Exhaustion for Remaining Individual Plaintiffs.

Plaintiffs ask the court to waive the requirement that they exhaust their administrative remedies for all Individual Plaintiffs who have not done so. The Secretary opposes this request, asserting that exhaustion is required before § 405(g) provides jurisdiction for judicial review. The Secretary argues that Plaintiffs' claims, although framed as resulting from a "clandestine policy," are merely claims that the services the Individual Plaintiffs received are "reasonable and necessary" under the Secretary's valid regulations and thus are in essence claims of "an aggregation of individual errors without more." (Doc. 25-1 at 31 (citing *Kildare v. Saenz*, 325 F.3d 1078, 1083 (9th Cir. 2003)) ("[A]ll that is alleged is a series of claimed irregularities in individual cases that is entirely dependent on the . . . underlying claims for benefits[.] An aggregation of individual errors without more does not meet the collaterality requirement as articulated in *City of New York*[.]")). Thus, the Secretary argues that the Individual Plaintiffs' claims

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following option: "I want the items and/or services . . . and I agree to pay for the items and/or services myself if Medicare or my other insurance doesn't pay."

fall squarely within the agency's expertise in implementing the Medicare Act and turn on the sort of factual development for which the administrative process is designed. The Secretary cites *Ringer*, 466 U.S. at 614, for these propositions.

In *Ringer*, the plaintiffs challenged the Secretary's policy of refusing coverage for a certain surgical procedure when used to treat a particular condition. *Id.* at 610. The Court declined to waive exhaustion because the plaintiffs were faulting the Secretary's decision that the treatment was not "reasonable and necessary," and thus their claims were substantive rather than procedural. *Id.* at 607, 614. The Court found plaintiffs' claims were not "collateral" because the plaintiffs sought "relief that [would] allow them to receive benefits yet bypass [the] administrative process altogether.'" *Id.* at 619, 624. Thus, despite any "procedural components" to the plaintiffs' claim, or their emphasis on the "presumptive nature of the Secretary's . . . rule," the claim was "essentially one requesting the payment of benefits[.]" *Id.* at 620, 624; *see also Saenz*, 325 F.3d at 1083 ("[w]ithout a specific policy, and with only allegations of idiosyncratic individual errors, whether [the defendants] committed the alleged errors must be determined in the context of each individual [plaintiff's administrative] proceedings").

Plaintiffs here contend the instant case is distinguishable from *Ringer* and argue that under Second Circuit precedent they have established everything that is required for waiver of exhaustion.

The decision whether waiver of exhaustion is appropriate is "intensely practical," rather than technical or formulaic. *Bowen v. City of New York*, 476 U.S. 467, 484 (1986) (internal citation omitted). Judicial waiver is appropriate where the plaintiffs' legal claims are collateral to their demand for benefits, where exhaustion would be futile, or where the harm suffered pending exhaustion would be irreparable. *See Mathews*, 424 U.S. at 330-32. "[N]o one factor is critical," and a court must balance "the competing considerations to arrive at a just result under the circumstances presented." *City of New York*, 742 F.2d at 736. In deciding whether waiver is appropriate, the court must:

> prevent[] premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct

> its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review.

Mich. Acad. of Family Physicians, 476 U.S. at 484 (quoting *Salfi*, 422 U.S. at 765).

As Plaintiffs correctly point out, courts have found waiver in cases where plaintiffs have sought to eradicate a "procedural irregularity" in the administrative appeals process, rather than challenge the application of valid regulations to their own individual cases. For example, in *City of New York*, a case involving claims for Social Security disability benefits, the plaintiffs alleged that, "[i]n disregard of the regulatory requirement to conduct an individualized assessment of the residual functional capacity of each claimant, [the Secretary], informally and without public disclosure, adopted an administrative practice that effectively imposed a presumption upon the determination of eligibility for . . . benefits." *City of New York*, 742 F.2d at 732. Specifically, the plaintiffs alleged that claimants whose mental illness did not meet particular diagnoses were presumed to have retained the ability to perform at least light unskilled work and were therefore ineligible for benefits. *Id.* The Second Circuit found that the plaintiffs' claim was "substantially collateral" to their individual claims for benefits because they complained "fundamentally of a procedural irregularity and not of the Secretary's substantive standards of eligibility," and because the suit did not seek an adjudication of the merits of the underlying claims. *Id.* at 737. The Second Circuit further found:

> Moreover, under the circumstances of this case, exhaustion of administrative remedies would have been futile. Although exhaustion might have resulted in recovery of retroactive benefits for some members of the class, as was also true in *Eldridge*, the administrative process cannot vindicate the procedural rights asserted in this litigation. The class members complain of a procedural irregularity—the failure of the Secretary to base eligibility determinations on individualized assessments of a claimant's residual functional capacity. This procedural right, guaranteed by the Secretary's regulations, cannot be vindicated by an ultimate determination of eligibility. For that reason further exhaustion justifiably may be waived.

Id.

In *City of New York*, the Second Circuit additionally observed that it could "discern no legitimate interest to be advanced by requiring plaintiffs to travel through the administrative maze as a prerequisite of a judicial hearing. This is not a case . . . where the claim asserted could benefit from further factual development or from the agency's 'experience and expertise[,]'" "[n]or is this a case where exhaustion serves to 'prevent[] premature interference with agency processes' or to allow the agency 'an opportunity to correct its own errors.'" *Id.* (internal citations omitted). The court pointed out that, "[a]s in *Eldridge* it is not realistic to 'expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single aid recipient . . . in an adjudicatory context.'" *Id.* (quoting *Eldridge*, 424 U.S. at 330).[5]

A similar approach was adopted in *New York v. Sullivan*, 906 F.2d 910, 914-18 (2d Cir. 1990), and *Fox v. Bowen*, 656 F. Supp. 1236, 1244 (D. Conn. 1987). In *Sullivan*, another Social Security disability case, the plaintiffs challenged the Secretary's exclusive reliance on certain treadmill testing, rather than the unique condition of each claimant, to determine the claimants' ability to work. *See Sullivan*, 906 F.2d at 914. In *Fox*, as here, the plaintiffs alleged that "the Secretary denies Medicare benefits on the basis of informal 'rules of thumb' that fail to take into account each claimant's individualized need[.]" *Fox*, 656 F. Supp. at 1244. For the same reasons set forth in *City of New York*, the courts in both cases granted judicial waiver of § 405(g)'s exhaustion requirement.

Here, as alleged in the Amended Complaint, the Improvement Standard is sufficiently analogous to the challenged policies in *City of New York*, *State of New York*,

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[5] The Secretary argues that *City of New York* is distinguishable because in that case the challenged policy was unlawful as applied to every claimant, regardless of the circumstances underlying each individual claim. By contrast, in this case, the Secretary contends that, pursuant to applicable regulations, there are circumstances in which it is perfectly acceptable for the Secretary to consider a beneficiary's stability and to deny Medicare coverage when there is no reasonable expectation that the beneficiary's condition will change. Plaintiffs, however, allege that the Improvement Standard is applied without regard to the particular services for which coverage is sought and without regard to the unique condition of each beneficiary. As alleged, the Improvement Standard thus constitutes the same "procedural irregularity" at issue in *City of New York*.

and *Fox* to warrant a conclusion that Plaintiffs' claims are substantially collateral to their individual claims for benefits. *See Abbey v. Sullivan*, 978 F.2d 37, 45 (2d Cir. 1992) (rejecting request for § 405(g) waiver, but noting that the case would be different had the plaintiffs alleged that "the Secretary [had] adopted a clandestine policy that violates the Medicare Act"). Unlike in *Ringer*, where a successful lawsuit would have meant that only "ministerial details" remained before the plaintiffs would receive benefits, 466 U.S. at 615, Plaintiffs have no guarantee of coverage even if they succeed on their claims. More importantly, Plaintiffs do not ask the court to adjudicate the merits of their individual claims or award them benefits; rather, they seek declaratory, injunctive, and mandamus relief. *See David v. Heckler*, 591 F. Supp. 1033, 1039 (S.D.N.Y. 1984) (noting "[t]he instant case is distinguishable [from *Ringer*] since plaintiffs seek prospective relief against a continuing illegal practice rather than specific benefits.").

Moreover, requiring Plaintiffs to pursue their claims at the administrative level would be futile even if they eventually obtained favorable decisions because such an outcome would not address the thrust of their Amended Complaint which is the use of the Improvement Standard in the lower levels of coverage determinations. Although the Secretary points to various instances in which the Medicare Appeals Council ("MAC") has overturned ALJ decisions because the ALJ failed "to conduct the kind of individualized inquiry called for by the applicable regulations and manual provisions," and improperly denied coverage because there was no expectation of improvement in the beneficiary's condition, *see* Doc. 25-1 at 32, as the Supreme Court has explained, "[s]uch observations . . . merely serve to remind us why exhaustion is the rule in the vast majority of cases; they do not aid the Court in deciding when exhaustion should be excused." *Mich. Acad. of Family Physicians*, 476 U.S. at 486.

Finally, in this case, the purposes of administrative review would not be served by requiring exhaustion because Plaintiffs allege violations of a procedural right—that is, the right to a coverage determination process free from the allegedly unlawful Improvement Standard—for which they seek relief which is simply not available in the context of an individual claim for benefits in an administrative review. As Judge Cabranes explained

in *Fox*: "It would be just as unrealistic in this case as it was in . . . *City of New York* to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single aid recipient . . . in an adjudicatory context." *Fox*, 656 F. Supp. at 1244 (internal quotation marks omitted); *see also Sullivan*, 906 F.2d at 918 ("Although exhaustion may have resulted in some individual members receiving benefits, the procedural right that the claimants sought to obtain, personalized determinations, could not have been vindicated by individual eligibility decisions.").[6]

For the foregoing reasons, the court concludes that the exhaustion requirement should be waived for Plaintiffs Boitano, Katz, and McGill. With the exhaustion requirement waived, § 405(g) provides the appropriate avenue for judicial review of the claims brought by all Individual Plaintiffs, with the exception of Ms. Masterman.

b. The Organizational Plaintiffs' Claims Under § 405(g).

Plaintiffs argue that the Organizational Plaintiffs "presented" their claims by writing letters to the Secretary complaining about the Improvement Standard. *See* Doc. 13 ¶¶ 92, 101, 109, 117, 124, 132, 141. They argue that the court should therefore waive exhaustion for the Organizational Plaintiffs for the same reasons supporting waiver for the Individual Plaintiffs.

In contrast, the Secretary contends that the Organizational Plaintiffs did not and cannot present their claims to the Secretary because the administrative review process is

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[6] The court need not find irreparable injury in order to conclude that waiver of exhaustion is appropriate. The Secretary argues Plaintiffs' claim of irreparable injury is a mere allegation. Plaintiffs counter that they have described "their serious chronic conditions, their advanced ages in some instances, and their desperate need for Medicare coverage of their health care." (Doc. 32 at 18.) As the *Ringer* Court observed, the "individual hardship resulting from delays in the administrative process" must be "balanced against the potential for overly casual or premature judicial intervention in an administrative system that processes literally millions of claims every year." *Ringer*, 466 U.S. at 627. The record before the court is not sufficient to properly perform this balancing test with regard to the Individual Plaintiffs. The court thus leaves unresolved whether the Individual Plaintiffs will suffer irreparable injury if the court refuses to waive exhaustion of their administrative remedies.

available only to program beneficiaries or their assignees, and the Organizational Plaintiffs are neither. At the same time, the Secretary point out that § 405(h) is the exclusive avenue of relief for the Organizational Plaintiffs and bars federal question jurisdiction under § 1331. The Secretary thus concludes the Organizational Plaintiffs' claims must be dismissed under § 405(g).

The Medicare Act's administrative appeals process is directed to appeals of unfavorable initial determinations. The right to appeal initial determinations denying or terminating coverage under Medicare Parts A, B, and C extends to beneficiaries and their assignees (usually the provider of services). *See* 42 C.F.R. §§ 405.710(a)-(b) (Part A); 405.801(b)(1) (Part B); 422.574(b) (Part C). These standards provide no mechanism for organizational plaintiffs to present their claims to the Secretary because they are neither beneficiaries nor assignees of beneficiaries, and they have not received an initial determination from which they can appeal. *See Nat'l Athletic Trainers' Ass'n v. HHS*, 455 F.3d 500, 503-508 (5th Cir. 2006) ("The parties agree that [the plaintiff association's] member[] [athletic trainers] cannot obtain administrative review because they are neither beneficiaries nor providers[.]").

In *Illinois Council*, 529 U.S. at 5, the Court decided, 5 to 4, that an association is neither entitled to "present" claims to an administrative agency nor entitled to establish federal question jurisdiction under § 1331. In that case, an association of nursing homes brought suit against the Secretary, challenging certain regulations governing the imposition of sanctions and remedies upon nursing homes that were found to be deficient in certain respects. *Id.* at 6. The plaintiff argued that federal question jurisdiction should be allowed under § 1331 because requiring presentment and exhaustion of administrative remedies would effectively preclude judicial review of its claims. *Id.* at 20. The plaintiff pointed out that it could not access the administrative appeals process reserved for "an institution or agency dissatisfied with a determination by the Secretary," 42 U.S.C. § 1395cc(h)(1) (governing appeals of determinations that a nursing home is noncompliant with the regulations), and therefore could not present a claim as required by § 405(g). *Id.* at 24. The Court rejected this argument, ruling that "[t]he [plaintiff] speaks only on

behalf of its member institutions, and thus has standing only because of the injury those members allegedly suffer. . . . [i]t is essentially their rights to review that are at stake. And the statutes that create the special [administrative] review channel adequately protect those rights." *Id.* (internal citations omitted). Thus, the Court reasoned that applying § 405(g) to claims brought by associations does not preclude judicial review of such claims, even though associations cannot themselves participate in administrative review. Instead, their claims must be presented and exhausted by the individual members on whose behalf the associations act.

The dissent in *Illinois Council* observed that the Court had not overruled *Mich. Acad. of Family Physicians*. The dissent contended that "*Michigan Academy* must have established a distinction between, on the one hand, a dispute over any particularized determination and, on the other hand, a challeng[e] to the validity of the Secretary's instructions and regulations." *Id.* at 1106-07 (quoting *Mich. Acad.*, 476 U.S. at 680). It characterized the claims before the Court in a manner strikingly similar to the claims of the Organizational Plaintiffs here:

> This case obviously falls into the latter category. Respondent in no way disputes any particularized determinations, but instead mounts a general challenge to the Secretary's regulations (and manual) . . . claiming that these were promulgated without notice and comment, are unconstitutionally vague, contravene the Medicare Act's requirement of enforcement consistency, and violate due process by affording insufficient administrative review. Like the *Michigan Academy* plaintiffs, who challenged the Secretary's regulation concerning the payment of benefits for physician's services . . . respondent may proceed in District Court under general federal-question jurisdiction.

Ill. Council, 529 U.S. at 38-39 (Thomas, J., dissenting). Justices Stevens, Kennedy, and Scalia joined in this portion of the dissent.

In this case, the Organizational Plaintiffs neither seek a fact dependent coverage determination nor a monetary recovery on their own behalf or on behalf of their members either now or in the future. Instead, they challenge the present and future use of the Improvement Standard in Medicare coverage determinations, which adversely impacts

their members. According to the *Illinois Council* majority, none of these distinctions matter:

> Despite the urging of the Council and supporting *amici*, we cannot distinguish *Salfi* and *Ringer* from the case before us. Those cases themselves foreclose distinctions based upon the "potential future" versus the "actual present" nature of the claim, the "general legal" versus the "fact-specific" nature of the challenge, the "collateral" versus "noncollateral" nature of the issues, or the "declaratory" versus "injunctive" nature of the relief sought. Nor can we accept a distinction that limits the scope of § 405(h) to claims for monetary benefits. Claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h). Section 1395ii's blanket incorporation of that provision into the Medicare Act as a whole certainly contains no such distinction. Nor for similar reasons can we here limit provisions to claims that involve "amounts."

Id. at 13-14.

Under *Illinois Council*, the Organizational Plaintiffs are also precluded from judicial review under § 1331 because "§ 405(g) contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court." *Ill. Council*, 529 U.S. at 15; *see also Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 456 (1999) ("judicial review under the federal-question statute, 28 U.S.C. § 1331, is precluded by 42 U.S.C. § 405(h)").

Plaintiffs nonetheless argue that *Illinois Council* allows "[t]he Association *or* its members [to] proceed . . . through the special review channel that the Medicare statutes create[.]" (Doc. 32 at 29 (citing *Ill. Council*, 529 U.S. at 5 and supplying emphasis)). They assert that all they need to do to invoke § 405(g) jurisdiction is to present their claims to the Secretary, and they have done so. They urge the court to adopt the approach taken in *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009). There, the district court found that the association plaintiffs had adequately "presented" their claims by mailing grievance letters to the Secretary, just as

the Organizational Plaintiffs have done here. *Id.* at 38-40. On appeal, the D.C. Court of Appeals endorsed this approach, noting that the plaintiffs had "cured the jurisdictional defect" by properly presenting their claims to the Commissioner of Social Security. *See Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010). Thus far, no other Circuit has adopted this approach.

Here, in the absence of guidance from the Supreme Court or, in the alternative, from the Second Circuit regarding how, if at all, an association may satisfy the non-waivable requirement of "presentment," the court declines to adopt the *Action Alliance* approach. *Illinois Council* does not permit presentment or processing of an organization's claims under § 405(g) even if this forecloses the organization from the administrative review process.[7] It also precludes § 1331 jurisdiction for an organization's claims arising under the Medicare Act. *See Ill. Council*, 529 U.S. at 15. In the absence of mandamus jurisdiction, *Illinois Council* thus leaves organizational plaintiffs with no means of obtaining judicial review of the Secretary's Medicare practices and procedures even if they "present" those challenges to the Secretary.

2. 28 U.S.C. § 1361 Mandamus Jurisdiction.

As an alternative to § 405(g) and § 1331, Plaintiffs argue that mandamus jurisdiction is available under 28 U.S.C. § 1361. The Secretary argues that the "extraordinary remedy" of mandamus jurisdiction is not appropriate in this case.

Pursuant to 28 U.S.C. § 1361, the "district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." Mandamus "may be awarded only if the plaintiff proves that (1) there is a clear right to the relief sought; (2) the Government has a plainly defined and peremptory duty to perform the act in question; and (3) there is no other adequate remedy available." *Benzman v. Whitman*, 523 F.3d 119, 132-33 (2d Cir. 2008). Mandamus "is an extraordinary remedy, available

[7] *See Am. Chiropractic Ass'n*, 431 F.3d at 817 ("The Association's objection that it could not itself become a party to the administrative proceedings is an objection the Supreme Court rejected in *Illinois Council*, 529 U.S. at 24.").

only in extraordinary circumstances." *Aref v. United States*, 452 F.3d 202, 206 (2d Cir. 2006) (quoting *In re United States*, 10 F.3d 931, 933 (2d Cir. 1993)).

Notwithstanding the high threshold for granting mandamus relief, mandamus jurisdiction over claims arising under the Medicare Act is not foreclosed as "it is settled in this and other circuits that, notwithstanding the sweeping language of section 405(h), mandamus jurisdiction is available under circumstances where the writ properly would issue." *City of New York*, 742 F.2d at 739.

In considering the secret and unlawful policy alleged in *City of New York*, the Second Circuit explained that "[t]he first two conditions [of mandamus jurisdiction] are obviously satisfied" because the "[Social Security] Act and the regulations enacted thereunder establish both the right and the duty—claimants' right to have eligibility determinations based on individualized assessments of residual functional capacity and the Secretary's duty to make such assessments and base eligibility determinations upon them." *Id.*; *see also Ellis v. Blum*, 643 F.2d 68, 78 (2d Cir. 1981) ("An impressive array of cases in this and other circuits has established that § 1361 jurisdiction will lie to review procedures employed in administering social security benefits."). Similarly here, the Medicare Act and the Secretary's regulations afford beneficiaries the right have to coverage determinations based on their unique medical conditions, and the Secretary has the duty to make such assessments and base coverage determinations upon them, rather than relying on the alleged Improvement Standard.

The Organizational Plaintiffs also satisfy the third requirement—that no other remedy be available—because neither § 405(g) nor § 1331 provides jurisdiction over their claims. The Second Circuit has recognized that plaintiffs who have not presented their claims to the Secretary may nonetheless invoke mandamus jurisdiction when it is otherwise appropriate, even though plaintiffs who have presented their claims but have failed to exhaust their administrative remedies cannot. *See City of New York*, 742 F.2d at 739 n.7 ("If the Supreme Court were to disagree with our ruling[] that class members are in compliance with the presentment . . . requirement[] . . . we believe mandamus jurisdiction would be available. However . . . if § 405(g) jurisdiction" is unavailable

because class members must exhaust their administrative remedies, "then mandamus jurisdiction would also be unavailable."); *Ellis*, 643 F.2d at 77 n.10 ("Even if we were to find jurisdiction under § 405(g), we might still be obliged to consider the possibility of mandamus jurisdiction . . . since § 405(g) would only furnish jurisdiction over those members of the alleged class who presented their claims to the Secretary.").

Here, having concluded that the Organizational Plaintiffs have not and cannot present their claims to the Secretary and thereby satisfy the non-waivable requirement of § 405(g), and having further found that they are foreclosed from invoking federal court jurisdiction under § 1331, the court concludes that in the absence of mandamus jurisdiction, the Organizational Plaintiffs would have no other remedy. In such extraordinary circumstances, mandamus provides the only available avenue of relief.

As the Secretary points out, however, even when mandamus relief *may* be granted, it remains "governed by equitable considerations and is to be granted only in the exercise of sound discretion." *Whitehouse v. Ill. Cent. R.R. Co.*, 349 U.S. 366, 373 (1955). Further, when "exercising its equitable powers" in this case, the court "is bound to give serious weight to the obviously disruptive effect which the grant of . . . relief . . . [i]s likely to have on the administrative process." *Sampson v. Murray*, 415 U.S. 61, 83 (1974). Based on the specific requests in Plaintiffs' Prayer for Relief (e.g., "ordering defendant . . . to review all adverse coverage decisions for the . . . class members that rely on the Improvement Standard"; "ordering defendant . . . to revise any rules, provisions, . . . or other written material . . . that supports and/or applies the Improvement Standard"), the Secretary contends that Plaintiffs seek the sort of "wholesale improvement of the [Medicare] program" that must be completed, if at all, "in the offices of [HHS] or the halls of Congress, where programmatic improvements are normally made." *Lujan*, 497 U.S. at 891. The Secretary also warns that awarding relief in this case could have costly consequences for the already cash-strapped Medicare program.

Plaintiffs counter that they are asking only for the correct implementation of the Medicare program, not wholesale changes to the program. As *City of New York* explained in the context of § 405(g):

> by ordering simply that the claims be reopened at the administrative level, the District Court showed proper respect for the administrative process. It did no more than the agency would have been called upon to do had it . . . been alerted to the charge that an undisclosed procedure was illegal and had improperly resolved innumerable claims.

City of New York, 476 U.S. at 486; *see also Fox*, 656 F. Supp. at 1250 (explaining that ordering the Secretary "to ensure that Medicare coverage determinations are made on the basis of individual patient's medical condition . . . will entail no greater fiscal and administrative burdens for the government than are contemplated by the applicable law and regulations.") (internal quotation marks omitted).

At the pleading stage, the court need not determine *whether to grant a writ of mandamus*, it need only determine whether, after an appropriate evidentiary showing and careful decision-making, a writ *could* issue. *See Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988) (the party seeking mandamus has the "burden of showing that its right to issuance of the writ is clear and indisputable.") (internal quotation marks and citation omitted). For purposes of surviving a motion to dismiss for lack of subject matter jurisdiction, Plaintiffs have sufficiently alleged mandamus jurisdiction pursuant to § 1361 over the claims of the Organizational Plaintiffs. The Secretary's motion to dismiss the Organizational Plaintiffs' claims for lack of subject matter jurisdiction under 28 U.S.C. § 1361 is hereby DENIED.

3. Dismissal for Lack of Standing: Plaintiffs Jimmo and K.R.

The Secretary contends that although Plaintiffs Jimmo and K.R. may seek judicial review under 42 U.S.C. § 405(g) because they have exhausted their administrative remedies, they lack Article III standing to challenge the Improvement Standard. The Secretary alleges that both Ms. Jimmo and K.R. lack standing because they were denied Medicare coverage for reasons independent of the Improvement Standard, and thus the relief Plaintiffs seek will not redress Ms. Jimmo's and K.R.'s injuries.

Under Article III of the Constitution, federal courts have jurisdiction only over "Cases" and "Controversies." U.S. CONST. art. III, § 2, cl. 1. Standing "is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan*, 504

U.S. at 560. If Plaintiffs lack standing, then the court has no subject matter jurisdiction to hear their claims. *See Carver v. City of New York*, 621 F.3d 221, 225 (2d Cir. 2010).

The "irreducible constitutional minimum of standing" contains three elements: (1) the plaintiff must have suffered injury in fact: an actual or imminent invasion of a legally protected, concrete and particularized interest; (2) there must be a causal connection between the alleged injury and the defendant's conduct at issue; and (3) it must be "likely," not "speculative," that the court can redress the injury. *Lujan*, 504 U.S. at 560-61. However, where, as here, "plaintiffs allege injury resulting from violation of a procedural right afforded to them by statute and designed to protect their threatened concrete interest, the courts relax—while not wholly eliminating—the issues of imminence and redressability but not the issues of injury in fact or causation." *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005).

A plaintiff's burden to establish the elements of standing "increases over the course of litigation." *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011). At the pleading stage, plaintiffs need only allege facts that establish a plausible claim to standing. *See Bldg. & Const. Trades Council of Buffalo, N.Y. and Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006) ("each element of standing 'must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation.'") (quoting *Lujan*, 504 U.S. at 561).

The "relaxed redressability" requirement for plaintiffs alleging deprivation of procedural rights means that "a plaintiff need not show that better procedures would have led to a different substantive result." *Renal Physicians Ass'n v. United States Dep't of HHS*, 489 F.3d 1267, 1278 (D.C. Cir. 2007). Nonetheless, a plaintiff must show that better procedures could *possibly* lead to an administrative decision in his or her favor and must satisfy the causation element by showing that the agency relied on the alleged wrongful procedure in reaching the decision regarding which the plaintiff complains. *See Sugar Cane Growers Co-op of Fla. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002) ("A plaintiff who alleges a deprivation of a procedural protection . . . [must] show that the

procedural step was connected to the substantive result."); *Banks v. Sec'y of Ind. Family & Soc. Servs. Admin.*, 997 F.2d 231, 239 (7th Cir. 1993) ("in order to have standing, the plaintiffs must also establish a 'fairly traceable' causal connection between the claimed injury and the challenged conduct of the defendant.") (quoting *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 72 (1978)).

In Ms. Jimmo's case, the Secretary contends that in denying coverage, the ALJ concluded that the "wound care provided to [Ms. Jimmo] . . . was not complex." (Doc. 25-3 at 7.) The ALJ further explained that Ms. Jimmo did not require observation and assessment because she "was stable and seen for frequent follow-ups at her physician's office for lesions and debridement. [Ms. Jimmo's] condition did not significantly change[] during the period at issue and the plan of care did not undergo changes." *Id.* On review, the MAC considered the administrative record and adopted the ALJ's decision for the same reasons. (Doc. 25-2 at 7-8.) Accordingly, the Secretary contends that Ms. Jimmo cannot establish that the outcome would have been different in the absence of the alleged Improvement Standard. The Secretary further argues that Ms. Jimmo lacks standing because she has already received the care and has not been held liable for any non-covered charges. She disagrees that any injury may be found based upon the fact that Ms. Jimmo will be presumed to have knowledge that the denied services will not be covered in the future.

The Secretary's argument assumes that the outcome for Ms. Jimmo would have been the same without the alleged Improvement Standard, but Plaintiffs' allegations support a contrary conclusion. The Amended Complaint alleges that in denying Ms. Jimmo coverage at the redetermination level, the Medicare contractor stated that Ms. Jimmo's "condition was stable with no acute changes." (Doc. 13 ¶ 50.) At the reconsideration level of review, the denial of coverage was grounded in part upon a conclusion that "[t]he likelihood of a change in the patient's condition requiring skilled nursing services was not supported in the documentation." (*Id.* ¶ 51.) The ALJ who reviewed the denial of coverage for Ms. Jimmo similarly concluded that "[o]bservation and assessment of the Beneficiary was not necessary as the Beneficiary was stable . . .

The Beneficiary's condition did not significantly changes [sic] during the period at issue and the plan of care did not undergo changes." (*Id.* ¶ 52.) Even the MAC decision, upon which the Secretary relies in challenging causation, found that Ms. Jimmo's "condition . . . [did not] change[] significantly during the period at issue." (*Id.* ¶ 54.) It can only be assumed that the MAC would have denied coverage even without this conclusion. Moreover, had the lower level adjudicators not employed an alleged Improvement Standard, the outcome could have been different. Plaintiffs further contend that even if Ms. Jimmo was not held financially responsible for the denied services, she suffers a detriment as a result of that determination as it will affect claims for benefits by her in the future.

Ms. Jimmo has sufficiently alleged that she experienced a number of coverage determinations that were arguably tainted by an unlawful Improvement Standard, including the Secretary's final decision. Moreover, the court cannot find, as a matter of law, that the outcome in Ms. Jimmo's case would have been the same even if the alleged Improvement Standard had not been applied. Ms. Jimmo has thus alleged a "'fairly traceable' causal connection between the claimed injury and the challenged conduct" of the defendant. *Duke Power Co.*, 438 U.S. at 72. The Secretary's motion to dismiss Ms. Jimmo's claims for lack of standing is therefore DENIED.

As for K.R., the Secretary contends she can no longer present a justiciable case-or-controversy because her claims are moot. After Plaintiffs filed the Amended Complaint, the MAC, in what constitutes the final decision of the Secretary, found that K.R. is not entitled to coverage because she was "not homebound" during the relevant time period. (Doc. 39-1 at 5.) Given this ruling, the Secretary argues that K.R. cannot show that any relief obtained in this case could potentially redress her injury. Plaintiffs argue that this conclusion is immaterial because "standing is determined by the plaintiff's situation at the time that the Amended Complaint is filed." (Doc. 49 at 3 n.2.) This is accurate, *see Comer v. Cisneros*, 37 F.3d 775, 787 (2d Cir. 1994), but ignores the additional requirement that, "[i]n order to satisfy the case-or-controversy requirement [of Article III], a party must, at all stages of the litigation, have an actual injury which is likely to be

redressed by a favorable judicial decision." *United States v. Blackburn*, 461 F.3d 259, 261 (2d Cir. 2006) (quoting *United States v. Mercurris*, 192 F.3d 290, 293 (2d Cir. 1999)). The issue thus becomes one of mootness rather than standing after the Amended Complaint is filed. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000). Accordingly, "if an event occurs during the course of the proceedings or on appeal 'that makes it impossible for the court to grant any effectual relief whatever to a prevailing party,' [the court] must dismiss the case." *United States v. Quattrone*, 402 F.3d 304, 308 (2d Cir. 2005) (quoting *Church of Scientology v. United States*, 506 U.S. 9, 12 (1992)).

Here, if events subsequent to the Amended Complaint are considered, K.R. cannot establish that she suffered an injury-in-fact as a result of the alleged Improvement Standard or that the outcome would have been different had the Improvement Standard not been used. However, the parties have not adequately briefed whether, if it is demonstrated that the alleged Improvement Standard was in fact applied to K.R.'s coverage determinations, it would still be "impossible for the court to grant [her] any effectual relief whatever." *Quattrone*, 402 F.3d at 308. In other words, the parties fail to address whether any relief remains available to K.R. even if her eligibility determination would not have been different. *See Sugar Cane Growers*, 289 F.3d at 94 ("A plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered."); *see also Sullivan*, 906 F.2d at 918 ("the procedural right that the claimants sought to obtain, personalized determinations, could not have been vindicated by individual eligibility decisions"); *City of New York*, 742 F.2d at 737 (the "procedural right, guaranteed by the Secretary's regulations, cannot be vindicated by an ultimate determination of eligibility.").

Because the Secretary has framed her request for dismissal of K.R.'s claims as one of standing, and because the court concludes that, at the time of the filing of the Amended Complaint, K.R. sufficiently alleged standing, the Secretary's motion to dismiss K.R.'s

claims for lack of standing is DENIED WITHOUT PREJUDICE TO RENEW ON THE GROUNDS OF MOOTNESS.[8]

4. Dismissal for Lack of Standing to Seek Injunctive Relief.

The Secretary next argues that the Individual Plaintiffs lack standing to pursue injunctive relief because they have not shown any likelihood that the Secretary will apply the Improvement Standard to their claims in the future. To seek prospective injunctive relief, a plaintiff must show either "continuing, present adverse effects" of the defendant's unlawful conduct that could be redressed through injunctive relief, *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983), or "a sufficient likelihood that he will be affected by the allegedly unlawful conduct in the future." *Wooden v. Bd. of Regents of Univ. Sys. of Ga.*, 247 F.3d 1262, 1283 (11th Cir. 2001). To demonstrate the likelihood of future harm, it is not enough that the plaintiff was harmed by the challenged conduct in the past; the plaintiff must instead show that he "is realistically threatened by a repetition of [the previous harm]." *Lyons*, 461 U.S. at 109; *see also White v. First Am. Registry*, 230 F.R.D. 365, 367 (S.D.N.Y. 2005) ("[W]here, as here, a plaintiff challenges an allegedly wrongful policy, he or she must allege credibly a 'realistic threat from the policy.'") (quoting *Friends of the Earth*, 528 U.S. at 184).

Courts agree that "when the threatened acts that will cause injury are . . . part of a policy," such as the Improvement Standard alleged in this case, "it is significantly more likely that the injury will occur again," and the existence of an official policy therefore supports the plaintiff's standing to pursue injunctive relief. *31 Foster Children v. Bush*, 329 F.3d 1255, 1266 (11th Cir. 2003); *see also Shain v. Ellison*, 356 F.3d 211, 216 (2d Cir. 2004) (explaining that "the existence of an official policy" makes repeated harm more probable). At the pleadings stage, the Individual Plaintiffs have alleged sufficient facts to establish standing to pursue injunctive relief.

The Secretary's motion to dismiss Plaintiffs' claims for injunctive relief for lack of standing is hereby DENIED.

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[8] In so ruling, the court does not foreclose the possibility that other challenges by the Secretary may also be renewed.

5. Dismissal of Organizational Plaintiffs' Claims for Lack of Standing.

Finally, the Secretary argues that at least six of the seven Organizational Plaintiffs lack standing because they have not sufficiently alleged that one of their members would have standing to bring these claims in his, her, or its own right. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977) ("an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit."). Plaintiffs disagree, and argue that they have adequately alleged associational standing at the pleading stage, with the exception of one organization.[9]

"Once a valid Article III case-or-controversy is present, the court's jurisdiction vests. The presence of additional parties, although they alone could [not] independently . . . satisfy Article III's requirements, does not itself destroy jurisdiction already established." *Ruiz v. Estelle*, 161 F.3d 814, 832 (5th Cir. 1998). "In accordance with this principle, the Supreme Court has repeatedly held that if one party has standing in an action, a court need not reach the issue of the standing of other parties when it makes no difference to the merits of the case." *Ry. Labor Execs.' Ass'n v. United States*, 987 F.2d 806, 810 (D.C. Cir. 1993) (citing *Doe v. Bolton*, 410 U.S. 179, 189 (1973)); *see also Horne v. Flores*, 129 S. Ct. 2579, 2592-93 (2009) ("Because the superintendent clearly has standing to challenge the lower courts' decisions, we need not consider whether the Legislators also have standing to do so."). Here, the presence of the Organizational Plaintiffs has no effect on the merits of the Individual Plaintiffs' claims. Accordingly, the

[9] At oral argument, Plaintiffs conceded that AAPM&R could not independently assert standing, because it makes no allegation that one of its members would have standing to sue other than the conclusory statement that "Members of AAPM&R would have standing to sue in their own right." (Doc. 13 ¶ 123.) Based upon this admission, the court hereby GRANTS the Secretary's motion to dismiss AAPM&R while GRANTING Plaintiffs leave to amend. *See* Fed. R. Civ. P. 15(a)(2) (instructing courts to "freely give leave [to amend the complaint] when justice so requires."); *Goldmark, Inc. v. Catlin Syndicate Ltd.*, 2011 WL 743568, at *5 (E.D.N.Y Feb. 24, 2011) (recognizing the "liberal spirit of Rule 15(a)" and granting plaintiff leave to amend the breach of contract claim in complaint to add claim of bad faith).

court need not address whether they could each independently establish standing at the pleadings stage.

For the foregoing reasons, the Secretary's Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction is GRANTED IN PART and DENIED IN PART. The court concludes that Plaintiffs have sufficiently alleged subject matter jurisdiction as to all of their claims, except for those of Ms. Masterman, which must be presented to the Secretary, and except for those of AAPM&R, for which Plaintiffs are granted leave to amend.

B. The Secretary's Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim.

The Secretary argues that the Amended Complaint fails to contain sufficient factual allegations to support a plausible claim for relief and therefore fails to satisfy Rule 8's pleading requirement. *See* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief"). In particular, the Secretary contends that while all of Plaintiffs' claims rely on the Secretary's use of the alleged "Improvement Standard," one cannot reasonably infer from the alleged facts that the Improvement Standard exists. According to the Secretary, this is true both because the Improvement Standard is inadequately defined, and because there are "obvious alternative" explanations for the complained of conduct that are far more plausible than a "clandestine" and "covert" policy. The Secretary further points out that its own regulations and policies, "while perhaps not using the exact term[,] effectively prohibit the use of a so-called 'Improvement Standard'- i.e., a standard that, as plaintiffs have characterized it, would require the denial of benefits in any case in which the treatment at issue is not expected to improve a beneficiary's condition." (Doc. 45 at 2.)

In response, Plaintiffs argue that the Improvement Standard's existence is supported by three categories of factual information: (1) various Local Coverage Determinations ("LCD") and provisions of the Medicare Benefit Policy Manual ("MBPM") that suggest the use of the Improvement Standard; (2) prior judicial decisions

in which courts have found that the Secretary employed something akin to the Improvement Standard; and (3) the written administrative decisions in each of the Individual Plaintiffs' cases. In addition, Plaintiffs rhetorically question whether seven national organizations that assist Medicare beneficiaries allegedly subject to the Improvement Standard would have joined the lawsuit if the Improvement Standard did not exist. *See* Doc. 32 at 37 ("Is the Secretary suggesting that these large and respected organizations are dissembling about the policy and its impact on their members and others whom they serve?").[10]

To survive a motion to dismiss under Rule 12(b)(6), the Amended Complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also* Fed. R. Civ. P. 8(a)(2). In *Iqbal*, the Supreme Court set forth a "two-pronged" approach for analyzing a Rule 12(b)(6) motion to dismiss. *Iqbal*, 129 S. Ct. at 1950. First, a court must accept a plaintiff's factual allegations as true and draw all reasonable inferences from those allegations in the plaintiff's favor. *Id.* at 1949-50. However, this assumption of truth does not apply to legal conclusions, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949. Second, a court must determine whether the Amended Complaint's "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief." *Id.* at 1950. Neither *Iqbal* nor *Twombly* impose "heightened" pleading standards. *See Arista Records, LLC v. Doe 3*, 604 F.3d 110, 119-21 (2d Cir. 2010) (rejecting a "heightened pleading standard" under *Iqbal/Twombly* and also rejecting the "contention that *Twombly* and *Iqbal* require the pleading of specific evidence or extra facts beyond what is needed to make the claim plausible.").

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

[10] The court does not address this claim further as it substitutes speculation for facts.

misconduct alleged." *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556-57). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

In considering whether the alleged facts "nudge" the plaintiffs' claims from merely "speculative" to "plausible," courts are instructed to rely on common sense, and to consider "obvious alternative explanations" to the plaintiffs' theory of liability. *See Twombly*, 550 U.S. at 567. However, the courts are not empowered to weigh the evidence, assess credibility, and choose the explanation they believe is most worthy of belief. *See Chao v. Ballista*, 630 F. Supp. 2d 170, 177 (D. Mass. 2009) ("[A] complaint should only be dismissed at the pleading stage where the allegations are so broad, and the alternative explanations are so overwhelming, that the claims no longer appear plausible."); *see also Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985) (when faced with a motion to dismiss for failure to state a claim, the court's task is "not to weigh the evidence that might be presented at trial but merely to determine whether the complaint itself is legally sufficient.").

Here, in seeking dismissal, the Secretary relies heavily on regulations and policies which forbid the application of anything resembling the Improvement Standard. *See* 42 C.F.R. § 409.44(a) (explaining that, under the home health benefit, Medicare coverage of skilled services is based on the "unique medical condition of the individual beneficiary"); MBPM, Ch. 7, § 20.3 (prohibiting the use of utilization screens or "rules of thumb" to make coverage decisions); 42 C.F.R. § 409.44(b)(3)(iii) (providing that the determination of whether a skilled service is reasonable and necessary "must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time"); 42 C.F.R. § 409.32(c) ("Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities."); Home Health Prospective Payment System Rate Update for Calendar Year 2011, 75 Fed. Reg. 70372, 70395 (Nov. 17, 2010) ("'Rules of thumb' in the Medicare medical review process are prohibited. . . . Medical denial decisions must be based on a detailed and

thorough analysis of the beneficiary's total condition and individual need for care."). Plaintiffs acknowledge the existence of those regulations and policies and do not question their validity, but argue that the Improvement Standard demonstrates they are being ignored. The *facts* they cite in support of the Improvement Standard's existence are decidedly scant.

For example, Plaintiffs cite LCD 23604 and 28290 as evidence of the Improvement Standard because, under the heading "Indications," it notes that "[t]here must be an expectation that the condition . . . will improve significantly within a reasonable and generally predictable period of time[,]" and under "Limitations" it states that "[p]hysical therapy is not covered when the documentation indicates that a patient has attained the therapy goals or has reached the point where no further significant practical improvement can be expected." *Id.* The Secretary, however, points out that this same LCD also states that the "design of a maintenance regimen/[home exercise plan] required to delay or minimize muscular and functional deterioration in patients suffering from a chronic disease may be considered reasonable and necessary[.]" Further, under "Maintenance Therapy," the LCD states that "[w]here repetitive services that are required to maintain function involve the use of complex and sophisticated procedures, the judgment and skill of a physical therapist might be required for the safe and effective rendition of such services. If the judgment and skill of a physical therapist is required to safely and effectively treat the illness or injury, the services may be covered as physical therapy services." *Id.* Thus, LCD 23604 does not, alone, establish an Improvement Standard.

Plaintiffs cite LCD 340 as evidence of the Improvement Standard because it provides for coverage when the "documentation supports the expectation that the beneficiary's condition will improve significantly in a reasonable and generally predictable period of time." *Id.* In the same paragraph, however, the LCD explains that coverage also applies when the services are "necessary for the establishment of a safe and

effective maintenance program required in connection with a specific disease state." *Id.*; *see also* 42 C.F.R. § 409.44(c)(2)(iii)(A)-(C).[11]

On balance, the LCDs and MBPMs, regarded in the light most favorable to Plaintiffs, do not provide sufficient factual support for Plaintiffs' allegations that an Improvement Standard is being used for the denial of Medicare coverage. This is hardly surprising, as Plaintiffs further allege that the Secretary's tacit endorsement of the Improvement Standard is both "covert" and "clandestine." *See Arista Records, LLC*, 604 F.3d at 120 ("The *Twombly* plausibility standard . . . does not prevent a plaintiff from pleading facts alleged upon information and belief where the facts are peculiarly within the possession and control of the defendant[.]") (internal quotation marks and citations omitted).

Plaintiffs further claim that the Improvement Standard "is apparent from the district court decisions that have repeatedly rejected the Improvement Standard over the years." (Doc. 32 at 36) (citing *Anderson v. Sebelius*, 2010 WL 4273238 (D. Vt. Oct. 25, 2010); *Papciak v. Sebelius*, 742 F. Supp. 2d 765 (W.D. Pa. 2010); *Folland v. Sullivan*, 1992 WL 295230 (D. Vt. Sept. 1, 1992); *Fox*, 656 F. Supp. 1236; *Rizzi v. Shalala*, 1994 WL 686630 (D. Conn. Sept. 29, 1994)). As an initial matter, Plaintiffs fail to explain why, in the absence of judicial notice, it would be appropriate for the court to consider such cases as factual allegations on a Rule 12(b)(6) motion to dismiss, particularly when the Amended Complaint does not mention them. At best, these cases support Plaintiffs' argument that their allegation of an Improvement Standard is neither fanciful, fantastic,

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[11] In their Opposition, Plaintiffs cite two additional LCDs, but neither appears to provide a basis to infer that the Improvement Standard exists. LCD 31530, which concerns occupational therapy, states that "[i]f the services required to maintain function involve the use of complex and sophisticated therapy procedures, the judgment and skill of a therapist may be necessary for the safe and effective delivery of such services." *Id.* LCD 28290, under the heading "Therapy for patients with symptoms from chronic disease," explains that Medicare covers the "design of a home therapy regimen required to delay or minimize muscular and functional deterioration in patients suffering from chronic disease." *Id.* Plaintiffs' MBPM citations, none of which are referenced in the Amended Complaint, fare no better. They do not establish an Improvement Standard and qualify any statement that appears to deny coverage merely because a condition is chronic or stable.

nor delusional. *See Gallop v. Cheney*, 642 F.3d 364, 368 (2d Cir. 2011) (dismissal of complaint was appropriate where "sufficiently well-pleaded facts are clearly baseless-that is, if they are fanciful, fantastic, or delusional.") (internal quotation marks omitted).

In any event, the court rejects Plaintiffs' invitation to look elsewhere for evidence of the Improvement Standard and focuses instead on the allegations of the Amended Complaint. With regard to each Individual Plaintiff, the Amended Complaint cites Agency decisions that are arguably consistent with the imposition of an Improvement Standard because adjudicators denied coverage based upon, *inter alia*, a conclusion that the beneficiary's condition would not improve.

The Secretary counters that the similarities between these Agency decisions are more obviously explained as legal errors in the application of valid regulations than the product of a nationwide covert policy to deny Medicare coverage on an unlawful basis. *See Bowen v. Yuckert*, 482 U.S. 137, 157 (1987) (explaining that the "Secretary faces an administrative task of staggering proportions in applying" the Social Security Act to process all disability benefits claims, and "[p]erfection in processing millions of such claims annually is impossible."); *Mercer v. Birchman*, 700 F.2d 828, 835 (2d Cir. 1983) ("[i]t has never been expected that" a "vast" claims-processing department of government "can achieve absolute procedural perfection."). The Secretary argues that the court must consider this obvious alternative basis and find Plaintiffs' claim implausible in the face of more likely and reasonable explanations. However, "[a] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 322 (2d Cir. 2010).

Applying the *Iqbal/Twombley* standard for a motion to dismiss under Rule 12(b)(6), the court cannot conclude as a matter of law that Plaintiffs' Improvement Standard theory is factually implausible when it is supported by at least *some* evidence in each of the Individual Plaintiffs' cases and where other plaintiffs have successfully demonstrated the use of illegal presumptions and rules of thumb much like Plaintiffs allege here. "Asking for plausible grounds to infer [application of the Improvement

Standard] does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [the Improvement Standard's existence]." *Twombly*, 550 U.S. at 556; *see also Price v. N.Y. State Bd. of Elections*, 540 F.3d 101, 107 (2d Cir. 2008) (dismissal is warranted only "if the facts as alleged are insufficient to raise a right to relief above the speculative level.") (internal quotation marks omitted). The Amended Complaint contains factual allegations beyond mere "labels and conclusions" coupled with a "formulaic recitation of the elements of a cause of action[,]" *Twombly*, 550 U.S. at 555, and "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 129 S. Ct. at 1949. Accordingly, at least with regard to the named Plaintiffs, the Amended Complaint states a claim for relief under Fed. R. Civ. P. 8.[12] The Secretary's motion to dismiss for failure to allege a plausible claim of relief is therefore DENIED.[13]

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[12] The court expresses no opinion regarding whether it would reach this same conclusion on a class wide basis.

[13] In a relatively cursory manner (Doc. 25-1 at 54-59), the Secretary also seeks dismissal of Plaintiffs' claims for failure to state a claim, arguing both the merits of Plaintiffs' claims and Plaintiffs' failure to demonstrate a sufficient legal basis for them. *See, e.g.*, Doc. 25-1 at 54 ("Plaintiffs' claims that alleged application of an 'Improvement Standard' violates the Due Process Clause of the Fifth Amendment . . . are meritless."); at 55 ("In any event, the procedures available to plaintiffs comport with due process requirements."); at 58 (arguing Improvement Standard, if it existed, would not require notice and comment for its promulgation); at 59 (arguing the Freedom of Information Act would not require the Federal Register to publish the Improvement Standard). In an equally cursory manner, Plaintiffs oppose dismissal. *See* Doc. 32 at 40-45. In the Secretary's Reply and the Plaintiffs' Surreply, the parties do not further pursue their arguments, nor did they adequately address them at oral argument. The court thus declines to address these alleged grounds for dismissal at this time without finding that dismissal has been waived. *See Ibarra v. City of Chicago*, 2011 WL 4583785, at *8 (N.D.Ill. Sept. 28, 2011) ("Given the complexity of the legal issues, the parties' cursory treatment of the issues, and the current stage of the litigation, the Court declines to dismiss Count II at this time."); *see also Allstate Ins. Co. v. Heil*, 2007 WL 4270355, at *2 n.2 (D. Haw. Dec. 6, 2007) ("Because the parties have not briefed the Rule 702 issue in anything more than a cursory way as part of their summary judgment arguments, the court declines to resolve the expert admissibility issues on the record before it.").

SO ORDERED.

Dated at Rutland, in the District of Vermont, this 25th day of October, 2011.

Christina Reiss, Chief Judge
United States District Court